

Abstract:

Process for the production of virus-inactivated human gammaglobulin G.

5 The gammaglobulin is extracted from a fraction isolated
by fractionation with ethanol in the presence of a
carbohydrate, and after reducing the content of contaminants
with PEG, it is applied to an anionic resin exchange column,
an effluent being obtained in which the PEG content is
10 subsequently reduced by ultrafiltration and which is
concentrated in order to carry out sequentially an optional
treatment at an acid pH and at least one of the following
steps of viral inactivation, consisting of pasteurisation
and a treatment with solvent/detergent, the product
15 afterwards being precipitated and washed with PEG in order
to eliminate any chemical viral inactivation reagents and
then, by solubilisation and change of pH, the protein
contaminants, and finally purified by ultrafiltration to
reduce the volume and the PEG content, then carrying out an
20 optional virus filtration and subsequent concentration to a
protein value of 5% or 10%.

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